UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,694	09/26/2005	Daniel F Hanley	58719(71699)	2172

21874 7590 08/20/2008

EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
08/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,694	HANLEY ET AL.	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-17 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 5/15/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

Scope of Enablement

The rejection of claims 1-20 under 35 USC 112, first paragraph, as not being enabled for preventing blood clots is maintained. This rejection is applicable to claims 1-4, 7-17 and 20 since claims 5, 6, 18 and 19 have been cancelled.

Applicant argues that the specification provides extensive teachings directed to preventing clot formation at page 3, lines 5-8. However, this section of the specification amounts to a mere allegation of prevention as opposed to a teaching. Applicants also argue that they have performed a clinical trial demonstrating prevention. However, these data were not supplied, and thus cannot be given any weight. This rejection is maintained given data supplied by Naff et al. which supports the unpredictable nature of treating blood clots. At page 5 of the previous action, the Naff reference taught that treatment with t-PA could actually clot volume in the initial 48 hour time period. Because the art has recognized that t-PA could fail to resolve clots, one of ordinary skill

in the art would not accept on its face that prevention of blood clots could be achieved by administering t-PA.

Indefiniteness—112, 2nd paragraph

The rejection of claims 14 and 15 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Claims 14 and 15 continue to recite "at least about", which makes the claims indefinite since it is not clear whether "at least" or "about" controls the metes and bounds of the claim limitation.

Claim Rejections - 35 USC § 102

The rejection of claims 1-4 and 6-10 were under 35 USC 102(a) as being anticipated by Naff et al. is maintained. This rejection is applicable to claims 1-4 and 8-10 since claim 6 has been cancelled.

Applicant argues that a Declaration submitted by the inventors, Neal Naff and Daniel Hanley, obviates the rejection. However, the applicants have not filed the required declaration which must be signed by the inventors i.e. the "In re Katz" declaration. Since the reference relied on in this rejection has been published before applicant's filing date, the rejection under 102(a) is proper.

New Rejection-102 (b)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 7-10, 12-15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayfrank et al., (Acta Neurochir (Wien) 1993).

Mayfrank et al., teach a method of treating blood clots in the brain by administering rtPA. (See Abstract.) Twelve patients with severe intraventricular haemorrhage (associated with intracerebral haemorrhage) were administered rtPA, as per claims 1-3. (Id.) External ventricular drainages was performed in all patients within 24hrs. for the onset of symptoms, As per claim 7. (Id.) Two to 5mg of rtPA were injected and repeated at intervals from 6 to 24 hours until CT scans demonstrated a substantial reduction of intraventricular blood, as per claims 8, 9, 10 and 20. (Id.)

They teach that rtPA has been known to lyse subarachnoid blood clots, as per claim 4. (See pg. 32, right column, 4th paragraph.) At page 34, Table 3 shows administration of rtPA at a 6 hour interval (claim 12), an 8 hour interval (claim 13), and a 12 hour interval (claim 15), which also meets the limitation of claim 14.

Claim Rejections - 35 USC § 103

The rejection of claims 1-20 under 35 USC 103(a) as being unpatentable over Naff et al. in view of Wright is maintained. This rejection is applicable to claims 1-4, 7-17 and 20 since claims 5, 6, 18 and 19 have been cancelled.

Applicants argue that the removal of Naff et al. as a reference obviates this rejection. However, the declaration which would remove Naff et al. as a refererence has not been signed and is therefore given no weight in regard to this rejection.

New Rejection-103(a)

Claims 11, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayfrank et al. (*supra*) as applied to claim 1-4, 7-10, 12-15 and 20 above.

Mayfrank et al., taught above, differs from the instant claims 11, 16 and 17 insofar as it does not teach a 4 hour interval, or stopping treatment when the blood clot is 80% of its original size, or when the blood clot is 80% of its original size about 3 days after the first administration of the thrombolytic agent.

It would have been obvious to a person having ordinary skill in the art to administer the rtPA of Mayfrank et al., at a about 4hours, since the term "about" is inclusive of higher of lower values. "About every 4 hours" more than likely includes the 6 hour interval of Mayfrank et al., especially in view of Conopco v. May, 24 USPQ2d 1721, 1736 (U.S. District Court, Eastern District of Missouri 1992). The court in that case found that four times the recited numerical value is within the scope of "about", where, based on the Doctrine of Equivalents, the compositions "perform substantially the same function in substantially the same manner." Here, administration of rtPA at an interval of "about every 4 hours" would perform substantially the same function in the same manner of the administration of rtPA at an interval of 6 hours.

It would have also been obvious to stop treatment when the blood clot is 80% of its original size, since Mayfrank teach stopping treatment until a substantial reduction of intravetricular blood. Mayfrank taught that ventricular size decrease was normal in all patients after 48 hours of treatment, and that the resolution of accompanying intraventricular haematomas (clots) seemed not to be accelerated by intraventricular rtPA injection. (See pg. 34, left col., 1st paragraph.) It may be that a substantial reduction of intraventricular blood occurs when the blood clot is 80% of it orginal size, since blood clots vary in size. In other words, a blood clot may be reduced in size enough by rtPA to be eliminated by the extraventricular drainage within 48 hours.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612